

**Status Report
The Birth Defect
Prevention Act of 1984**

A Report to the Legislature



**California Environmental Protection Agency
DEPARTMENT OF PESTICIDE REGULATION**

June 1996

California Environmental Protection Agency
DEPARTMENT OF PESTICIDE REGULATION

Pete Wilson, Governor

James M. Strock
Secretary for Environmental Protection

James W. Wells, Director
Department of Pesticide Regulation

EXECUTIVE SUMMARY
of the June 1996 Report to the Legislature

PURPOSE:

This report provides information on the status of the chronic health effects studies required by the Birth Defect Prevention Act (the Act) for the 200 pesticide active ingredients identified as having the most significant data gaps, widespread use, and which were suspected of being hazardous to people. For these 200 priority active ingredients, the required health effects studies were due to the Department of Pesticide Regulation (DPR) by March 30, 1996. Those active ingredients for which pesticide registrants failed to submit the required studies are identified as having data gaps. A "data gap" means that DPR does not have on file adequate health effects studies in the following areas: chronic toxicity, mutagenicity, neurotoxicity, oncogenicity, reproductive effects, and teratology. Pesticide registrants are in compliance with the Act when final reports for required studies are received by DPR, unless later evaluation determines that any study is not adequate.

This is the required annual report to the Legislature on the data gaps that remain for the priority active ingredients, as required by 1991 legislation (SB 550) amending the Act.

BACKGROUND:

The Act requires DPR to acquire certain toxicological data for registered pesticide active ingredients in order to make a scientific determination that their continued uses will not cause significant adverse health effects. Pesticide products containing active ingredients identified as having the potential to cause unmitigated significant adverse health effects will be canceled or suspended.

In January 1986, each registrant of any pesticide product containing any of the 200 priority active ingredients was notified of the required studies needed to fill the data gaps. Many of the studies originally submitted did not meet the U.S. Environmental Protection Agency (U.S. EPA) guidelines for conducting such studies. Because these studies were done some years ago, many registrants were unable to obtain additional data from the laboratories which conducted the original studies; thus, the studies could not be upgraded. Registrants then began contracting with laboratories to begin new studies. However, most registrants failed to complete and submit new chronic health effects studies within the time frames in the law.

Executive Summary
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In 1991, the Act was amended (SB 550) strengthening the Director's authority to suspend products for noncompliance and requiring the Director to initiate the suspension process for products containing active ingredients for which all required health effects studies were not submitted by December 31, 1991. Amendments provided that under certain conditions registrants and others could petition for additional time to submit the data. However, the law specifies that no pesticide product containing any of the 200 priority active ingredients for which the required studies have not been submitted by March 30, 1996, shall remain registered. Another amendment requires DPR to report to the appropriate committees of the Legislature on the specific data gaps remaining for the priority 200 active ingredients.

In a March 1996 amendment to the Act, continued registration of two active ingredients is allowed while studies are being completed. The studies for these active ingredients, methyl bromide and pentachlorophenol, are due by December 31, 1997.

REPORT SUMMARY:

Of the 200 priority active ingredients, there remain 149 registered. Most of the 51 active ingredients no longer registered were voluntarily withdrawn by registrants who chose not to support continued registration by providing studies required either by the State or by U.S. EPA. Several active ingredients among these 51 were withdrawn by registrants following product suspension action in California. Several other active ingredients were withdrawn before suspension actions could be taken. For the active ingredients that remain registered, the report identifies those studies on file with adequate data, the studies to be completed for methyl bromide and pentachlorophenol, the studies at DPR pending evaluation, and the studies with inadequate data submitted. Certain studies for which the data were found to be inadequate can be upgraded with the submission of additional information. If studies cannot be upgraded by submission of additional data, the products containing those active ingredients are in the process of being suspended.

The data requirements for antimicrobial pesticide active ingredients (e.g., sanitizers and disinfectants) vary depending on the registered uses. Therefore, for certain antimicrobial products, a complete set of adequate data are on file even though this report shows inadequate or no data for certain study categories. For example, products to which human exposure is determined to be low are required to have on file only one teratogenicity study and three mutagenicity studies.

CONCLUSIONS:

Of the priority 200 active ingredients, there remain 149 registered. There are 117 active ingredients with a complete set of adequate data on file, and ten active ingredients for which DPR has sufficient data to assess potential adverse health effects. Studies have been submitted to DPR for 14 active ingredients, and are awaiting review. There are six active ingredients with data gaps. Suspension actions have been initiated for products containing five of these, and an exemption request has been received for the other one. Two active ingredients, methyl bromide and pentachlorophenol, have studies in progress, for which the deadline to submit data is December 31, 1997.

The attached table summarizes the June 1996 annual report.

Attachment

BIRTH DEFECT PREVENTION ACT
REPORT SUMMARY
June 1996

Information on the status of the priority 200 pesticide active ingredients [Food and Agricultural Code Section 13127(a)]

ACTIVE INGREDIENT STATUS	NUMBER OF ACTIVE INGREDIENTS
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Identified for the 1986 data call-in	200
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No longer registered	51
Registrations for five were suspended before being withdrawn:	
Cyhexatin	
Dimethylphthalate	
Ferbam	
Naphthalene	
Parathion	

Currently registered	<hr/> 149
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A full set of adequate studies is on file	117
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Studies are not required at this time (adequate data exist to assess potential adverse health effects)	10
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All studies submitted (one or more pending review and/or one or more upgradable)	14
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Active ingredients with data gaps	<hr/> 8
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A full set of adequate studies is not on file	8
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One or more studies are in progress	2
Deadline for submitting data extended to December 31, 1997, as authorized in section 13127.32:	

Methyl Bromide	
Pentachlorophenol	

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ACTIVE INGREDIENT STATUS

NUMBER OF ACTIVE INGREDIENTS

Suspension actions taken or pending
for all products containing the active ingredient 6

One or more studies not upgradable: 1
Acrolein¹

Active ingredients suspended: 2
Bendiocarb
Coumaphos

Notices of Intent to Suspend Registration
were issued because required data were not
submitted by March 30, 1996: 3
Chloroneb
Creosote
Petroleum Distillates, Aromatic

TOTAL OF 200 ACTIVE INGREDIENTS

Suspension actions taken for one or more products, but not all
products containing the active ingredient. These active
ingredients are considered to have a full set of valid studies on
file for all other products.

Boric Acid²
Diphacinone³
Formaldehyde⁴

¹A request for exemption from the data requirements pursuant
to section 13127 (e) (1) is under review.

²Only three boric acid products out of 45 had suspension
actions taken.

³Notices of Intent to Suspend Registration for seven of
52 products containing diphacinone were issued because the data
requirements for these seven products are different and the data
were not submitted by March 30, 1996. The data requirements are
different because the registered uses have potentially greater
human exposure.

⁴A Notice of Intent to Suspend Registration was issued for
one product containing formaldehyde, because the data
requirements for this product are different and the data were not
submitted by March 30, 1996. The data requirements are different
because the registered uses have potentially greater human
exposure.

REPORT TO THE LEGISLATURE
BIRTH DEFECT PREVENTION ACT OF 1984

JUNE 1996

The Birth Defect Prevention Act of 1984, as amended, requires the Department of Pesticide Regulation to report annually on the status of specific data gaps remaining for pesticide products containing any active ingredient identified pursuant to Food and Agricultural Code section 13127, subdivision (a). The deadline for submission of data to fill data gaps was March 30, 1996. The registrations of pesticide products containing an active ingredient for which a data gap remains are being suspended. This is the required annual report on data gaps remaining for the priority active ingredients.

This report lists each active ingredient in alphabetical order and shows the status of the health effects data for each required study.

STATUS OF THE DATA

Specific statements are used to report the status of the required health effects data for each pesticide active ingredient in the list that follows. An explanation of each statement used under the column "Status of Data" is given below.

Adequate data on file - The data on file for the study category are adequate, and no additional data are required.

Data submitted under review - Data were received for the study category and are currently being reviewed. The data submitter will be informed of the status when the review is completed.

Request for reconsideration under review - A petition for reconsideration of the acceptability of the study was received and is currently being reviewed. The data submitter will be informed of the status when the review is completed.

Data not adequate - Data on file are not adequate, and may not be upgraded.

Data not adequate, may be upgraded - Data on file are not adequate, but may be upgraded with submission of additional information. A petition for reconsideration has not been received at this time.

No data on file - There are no data on file.

Data not required at this time - Data are not required for this study category at this time.

Commitment to generate data - A commitment was received to initiate the study and submit data by December 31, 1997.

The following is an explanation of the statements used when the individual study categories are not listed under the chemical name:

Health effects data are not required at this time - Adequate data exist to assess potential adverse health effects.

This active ingredient is no longer registered - There are no pesticide products currently registered in California containing this active ingredient.

There are no remaining data gaps for this chemical at this time - All of the required health effects studies were submitted and found to be adequate.

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
BIRTH DEFECT PREVENTION ACT OF 1984 (SB950)
MANDATORY HEALTH EFFECTS DATA BASE
(CURRENT STATUS BY STUDY CATEGORY)

Chemical Name: ACEPHATE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: ACROLEIN

Study Category	Study Status
Chronic Feeding - Rat.....	Data not adequate.
Chronic Feeding - Dog.....	Adequate data on file.
Oncogenicity - Rat.....	Adequate data on file.
Oncogenicity - Mouse.....	Data not adequate.
Reproduction - Rodent.....	Adequate data on file.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

Chemical Name: ALACHLOR

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: ALDICARB

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: ALDRIN

This Active Ingredient is no Longer Registered.

Chemical Name: ALKYL(50%Cl14,40%Cl12,10%Cl16)DIMETHYLBENZYL AMMONIUM CHLORIDE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: ALLETHRIN

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: ALUMINUM PHOSPHIDE

Health Effects Data are Not Required at This Time.

Chemical Name: AMITRAZ

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: AMITROLE

This Active Ingredient is no Longer Registered.

Chemical Name: ARSENIC PENTOXIDE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: ARSENIC TRIOXIDE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: ASULAM, SODIUM SALT

This Active Ingredient is no Longer Registered.

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
BIRTH DEFECT PREVENTION ACT OF 1984 (SB950)
MANDATORY HEALTH EFFECTS DATA BASE
(CURRENT STATUS BY STUDY CATEGORY)

Chemical Name: ATRAZINE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: AZINPHOS-METHYL

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: BARBAN

This Active Ingredient is no Longer Registered.

Chemical Name: BENDIOCARB

Study Category	Study Status
Chronic Feeding - Rat.....	Data not adequate.
Chronic Feeding - Dog.....	Adequate data on file.
Oncogenicity - Rat.....	Data not adequate.
Oncogenicity - Mouse.....	Adequate data on file.
Reproduction - Rodent.....	Data not adequate.
Teratology - Rat.....	Data submitted under review.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

Chemical Name: BENOMYL

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: BENTAZON,SODIUM SALT

Study Category	Study Status
Chronic Feeding - Rat.....	Adequate data on file.
Chronic Feeding - Dog.....	Data not adequate, may be upgraded.
Oncogenicity - Rat.....	Adequate data on file.
Oncogenicity - Mouse.....	Adequate data on file.
Reproduction - Rodent.....	Adequate data on file.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

Chemical Name: BORIC ACID

Study Category	Study Status
Chronic Feeding - Rat.....	Data not adequate.
Chronic Feeding - Dog.....	Data not adequate.
Oncogenicity - Rat.....	No data on file.
Oncogenicity - Mouse.....	Adequate data on file.
Reproduction - Rodent.....	Data not adequate.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

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MANDATORY HEALTH EFFECTS DATA BASE
(CURRENT STATUS BY STUDY CATEGORY)

Chemical Name: BROMACIL

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: BROMOXINIL OCTANOATE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: CAPTAFOL

This Active Ingredient is no Longer Registered.

Chemical Name: CAPTAN

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: CARBARYL

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: CARBOFURAN

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: CARBON TETRACHLORIDE

This Active Ingredient is no Longer Registered.

Chemical Name: CARBOXIN

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: CHLORAMBEN

This Active Ingredient is no Longer Registered.

Chemical Name: CHLORDANE

This Active Ingredient is no Longer Registered.

Chemical Name: CHLORDIMEFORM

This Active Ingredient is no Longer Registered.

Chemical Name: CHLORFLURENOL, METHYL ESTER

This Active Ingredient is no Longer Registered.

Chemical Name: CHLORINE

Health Effects Data are Not Required at This Time.

Chemical Name: CHLOROBENZILATE

This Active Ingredient is no Longer Registered.

Chemical Name: CHLORONEB

Study Category	Study Status
Chronic Feeding - Rat.....	Data not adequate.
Chronic Feeding - Dog.....	Data not adequate.
Oncogenicity - Rat.....	No data on file.
Oncogenicity - Mouse.....	No data on file.
Reproduction - Rodent.....	Data not adequate.
Teratology - Rat.....	Data not adequate.
Teratology - Rabbit.....	Data not adequate.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Data not adequate.
Mutagenicity - DNA Damage.....	Data not adequate.
Neurotoxicity - Hen.....	Data not required at this time.

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MANDATORY HEALTH EFFECTS DATA BASE
(CURRENT STATUS BY STUDY CATEGORY)

Chemical Name: ORTHO-BENZYL-PARA-CHLOROPHENOL

Study Category	Study Status
Chronic Feeding - Rat.....	Data not adequate.
Chronic Feeding - Dog.....	No data on file.
Oncogenicity - Rat.....	Data not adequate, may be upgraded.
Oncogenicity - Mouse.....	Data not adequate, may be upgraded.
Reproduction - Rodent.....	No data on file.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

Chemical Name: CHLOROPICRIN

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: CHLOROTHALONIL

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: CHLORPYRIFOS

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: CHLORSULFURON

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: CHLORTHAL-DIMETHYL

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: COPPER HYDROXIDE

Health Effects Data are Not Required at This Time.

Chemical Name: COUMAPHOS

Study Category	Study Status
Chronic Feeding - Rat.....	Adequate data on file.
Chronic Feeding - Dog.....	Data not adequate.
Oncogenicity - Rat.....	Adequate data on file.
Oncogenicity - Mouse.....	Data not adequate.
Reproduction - Rodent.....	Data not adequate.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Adequate data on file.

Chemical Name: CREOSOTE

Study Category	Study Status
Chronic Feeding - Rat.....	Data not required at this time.
Chronic Feeding - Dog.....	Data not required at this time.
Oncogenicity - Rat.....	Data not required at this time.
Oncogenicity - Mouse.....	Commitment to generate data.
Reproduction - Rodent.....	Adequate data on file.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	No data on file.
Neurotoxicity - Hen.....	Data not required at this time.

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
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MANDATORY HEALTH EFFECTS DATA BASE
(CURRENT STATUS BY STUDY CATEGORY)

Chemical Name: CRYOLITE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: CYANAZINE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: CYANURIC ACID, MONOSODIUM SALT

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: CYCLOATE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: CYHEXATIN

This Active Ingredient is no Longer Registered.

Chemical Name: 2,4-D

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: 2,4-D, DIMETHYLAMINE SALT

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: DAMINOZIDE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: DDVP

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: DEET

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: DEMETON

This Active Ingredient is no Longer Registered.

Chemical Name: DIAZINON

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: DICAMBA

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: DICHLOBENIL

Study Category	Study Status
Chronic Feeding - Rat.....	Adequate data on file.
Chronic Feeding - Dog.....	Data submitted under review.
Oncogenicity - Rat.....	Adequate data on file.
Oncogenicity - Mouse.....	Adequate data on file.
Reproduction - Rodent.....	Adequate data on file.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
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MANDATORY HEALTH EFFECTS DATA BASE
(CURRENT STATUS BY STUDY CATEGORY)

Chemical Name: PARA-DICHLOROBENZENE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: 1,2-DICHLOROPROPANE, 1,3-DICHLOROPROPENE & RELATED C-3 COMPOUNDS

This Active Ingredient is no Longer Registered.

Chemical Name: 1,3-DICHLOROPROPENE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: DICLOFOP METHYL

Study Category	Study Status
Chronic Feeding - Rat.....	Data not adequate.
Chronic Feeding - Dog.....	Data not adequate.
Oncogenicity - Rat.....	Data not adequate.
Oncogenicity - Mouse.....	Data not adequate.
Reproduction - Rodent.....	Data not adequate.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Data not adequate.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

Chemical Name: DICOFOF

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: DIDECYL DIMETHYL AMMONIUM CHLORIDE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: DIETHATYL-ETHYL

This Active Ingredient is no Longer Registered.

Chemical Name: DIMETHOATE

Study Category	Study Status
Chronic Feeding - Rat.....	Adequate data on file.
Chronic Feeding - Dog.....	Adequate data on file.
Oncogenicity - Rat.....	Adequate data on file.
Oncogenicity - Mouse.....	Adequate data on file.
Reproduction - Rodent.....	Request for reconsideration under review.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Adequate data on file.

Chemical Name: DIMETHYLPHTHALATE

This Active Ingredient is no Longer Registered.

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MANDATORY HEALTH EFFECTS DATA BASE
(CURRENT STATUS BY STUDY CATEGORY)

Chemical Name: FENAMIPHOS

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: FENARIMOL

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: FENSULFOTHION

This Active Ingredient is no Longer Registered.

Chemical Name: FENTHION

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: FERBAM

This Active Ingredient is no Longer Registered.

Chemical Name: FLUCHLORALIN

This Active Ingredient is no Longer Registered.

Chemical Name: FLUCYTHRINATE

This Active Ingredient is no Longer Registered.

Chemical Name: FLUOMETURON

This Active Ingredient is no Longer Registered.

Chemical Name: FLUVALINATE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: FOLPET

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: FORMALDEHYDE

Study Category	Study Status
Chronic Feeding - Rat.....	Data not adequate, may be upgraded.
Chronic Feeding - Dog.....	Data not adequate, may be upgraded.
Oncogenicity - Rat.....	Data not adequate, may be upgraded.
Oncogenicity - Mouse.....	Adequate data on file.
Reproduction - Rodent.....	Data not adequate.
Teratology - Rat.....	Data not adequate, may be upgraded.
Teratology - Rabbit.....	Data not adequate.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

Chemical Name: FOSAMINE, AMMONIUM SALT

This Active Ingredient is no Longer Registered.

Chemical Name: GLYPHOSATE, ISOPROPYLAMINE SALT

There are No Remaining Data Gaps for This Chemical at This Time.

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
BIRTH DEFECT PREVENTION ACT OF 1984 (SB950)
MANDATORY HEALTH EFFECTS DATA BASE
(CURRENT STATUS BY STUDY CATEGORY)

Chemical Name: HEPTACHLOR

This Active Ingredient is no Longer Registered.

Chemical Name: HYDROGEN CHLORIDE

Health Effects Data are Not Required at This Time.

Chemical Name: IMAZALIL

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: IPRODIONE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: ISOPROPYL ALCOHOL

Health Effects Data are Not Required at This Time.

Chemical Name: LINDANE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: LINURON

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: LITHIUM HYPOCHLORITE

Study Category	Study Status
Chronic Feeding - Rat.....	No data on file.
Chronic Feeding - Dog.....	No data on file.
Oncogenicity - Rat.....	No data on file.
Oncogenicity - Mouse.....	No data on file.
Reproduction - Rodent.....	No data on file.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Data not adequate.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

Chemical Name: MALATHION

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: MALEIC HYDRAZIDE, DIETHANOLAMINE SALT

This Active Ingredient is no Longer Registered.

Chemical Name: MALEIC HYDRAZIDE, POTASSIUM SALT

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: MANCOZEB

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: MANEB

There are No Remaining Data Gaps for This Chemical at This Time.

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
BIRTH DEFECT PREVENTION ACT OF 1984 (SB950)
MANDATORY HEALTH EFFECTS DATA BASE
(CURRENT STATUS BY STUDY CATEGORY)

Chemical Name: 2,4-DINITROPHENOL

This Active Ingredient is no Longer Registered.

Chemical Name: DINOCAF

This Active Ingredient is no Longer Registered.

Chemical Name: DINOSEB

This Active Ingredient is no Longer Registered.

Chemical Name: DIOXATHION

This Active Ingredient is no Longer Registered.

Chemical Name: DIPHACINONE

Study Category	Study Status
Chronic Feeding - Rat.....	No data on file.
Chronic Feeding - Dog.....	No data on file.
Oncogenicity - Rat.....	No data on file.
Oncogenicity - Mouse.....	No data on file.
Reproduction - Rodent.....	No data on file.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	No data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

Chemical Name: DIPHENAMID

This Active Ingredient is no Longer Registered.

Chemical Name: DIPHENYLAMINE

Study Category	Study Status
Chronic Feeding - Rat.....	Request for reconsideration under review.
Chronic Feeding - Dog.....	Request for reconsideration under review.
Oncogenicity - Rat.....	Request for reconsideration under review.
Oncogenicity - Mouse.....	Request for reconsideration under review.
Reproduction - Rodent.....	Adequate data on file.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

Chemical Name: DIPROPYL ISOCINCHOMERONATE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: DIQUAT DIBROMIDE

There are No Remaining Data Gaps for This Chemical at This Time.

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Chemical Name: DIURON

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: ENDOSULFAN

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: ENDOTHALL, MONO (N,N-DIMETHYL ALKYLAMINE) SALT

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: ENDRIN

This Active Ingredient is no Longer Registered.

Chemical Name: EPN

This Active Ingredient is no Longer Registered.

Chemical Name: EPTC

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: ETHALFLURALIN

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: ETHEPHON

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: ETHOFUMESATE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: ETHOPROP

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: ETHYL ALCOHOL

Health Effects Data are Not Required at This Time.

Chemical Name: ETHYLENE DIBROMIDE

This Active Ingredient is no Longer Registered.

Chemical Name: ETHYLENE DICHLORIDE

This Active Ingredient is no Longer Registered.

Chemical Name: ETHYLENE GLYCOL, MONOMETHYL ETHER

Health Effects Data are Not Required at This Time.

Chemical Name: ETHYLENE OXIDE

Study Category	Study Status
Chronic Feeding - Rat.....	Adequate data on file.
Chronic Feeding - Dog.....	Request for reconsideration under review.
Oncogenicity - Rat.....	Adequate data on file.
Oncogenicity - Mouse.....	Adequate data on file.
Reproduction - Rodent.....	Adequate data on file.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
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(CURRENT STATUS BY STUDY CATEGORY)

Chemical Name: MEFLUIDIDE, DIETHANOLAMINE SALT

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: METALDEHYDE

Study Category	Study Status
Chronic Feeding - Rat.....	Adequate data on file.
Chronic Feeding - Dog.....	Adequate data on file.
Oncogenicity - Rat.....	Adequate data on file.
Oncogenicity - Mouse.....	Commitment to generate data.
Reproduction - Rodent.....	Adequate data on file.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

Chemical Name: METAM-SODIUM

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: METHIDATHION

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: METHOMYL

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: METHYL BROMIDE

Study Category	Study Status
Chronic Feeding - Rat.....	Commitment to generate data.
Chronic Feeding - Dog.....	Data submitted under review.
Oncogenicity - Rat.....	Adequate data on file.
Oncogenicity - Mouse.....	Adequate data on file.
Reproduction - Rodent.....	Adequate data on file.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

Chemical Name: METHYL PARATHION

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: METHYLENE CHLORIDE

This Active Ingredient is no Longer Registered.

Chemical Name: METHYLENEBIS (THIOCYANATE)

Study Category	Study Status
Chronic Feeding - Rat.....	Data submitted under review.
Chronic Feeding - Dog.....	Adequate data on file.
Oncogenicity - Rat.....	Data submitted under review.
Oncogenicity - Mouse.....	Data submitted under review.
Reproduction - Rodent.....	Request for reconsideration under review.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
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MANDATORY HEALTH EFFECTS DATA BASE
(CURRENT STATUS BY STUDY CATEGORY)

Chemical Name: METOLACHLOR

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: METRIBUZIN

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: MEVINPHOS

This Active Ingredient is no Longer Registered.

Chemical Name: MOLINATE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: MONOCROTOPHOS

This Active Ingredient is no Longer Registered.

Chemical Name: MSMA

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: NALED

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: NAPHTHALENE

This Active Ingredient is no Longer Registered.

Chemical Name: NAPROPAMIDE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: NAPTALAM, SODIUM SALT

This Active Ingredient is no Longer Registered.

Chemical Name: NITRAPYRIN

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: NORFLURAZON

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: OCTYLBICYCLOHEPTENE DICARBOXIMIDE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: ORYZALIN

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: OKADIAZON

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: OKAMYL

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: OXYCARBOXIN

This Active Ingredient is no Longer Registered.

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MANDATORY HEALTH EFFECTS DATA BASE
(CURRENT STATUS BY STUDY CATEGORY)

Chemical Name: OXYFLUORFEN

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: OXYTHIOQUINOX

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: PARAQUAT DICHLORIDE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: PARATHION

This Active Ingredient is no Longer Registered.

Chemical Name: PCNB

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: PCP

Study Category	Study Status
Chronic Feeding - Rat.....	Commitment to generate data.
Chronic Feeding - Dog.....	Adequate data on file.
Oncogenicity - Rat.....	Commitment to generate data.
Oncogenicity - Mouse.....	Adequate data on file.
Reproduction - Rodent.....	Commitment to generate data.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

Chemical Name: PEBULATE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: PENDIMETHALIN

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: PERMETHRIN

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: PETROLEUM DISTILLATES, AROMATIC

Study Category	Study Status
Chronic Feeding - Rat.....	No data on file.
Chronic Feeding - Dog.....	No data on file.
Oncogenicity - Rat.....	No data on file.
Oncogenicity - Mouse.....	Data not adequate.
Reproduction - Rodent.....	No data on file.
Teratology - Rat.....	No data on file.
Teratology - Rabbit.....	No data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Data not adequate.
Mutagenicity - DNA Damage.....	No data on file.
Neurotoxicity - Hen.....	Data not required at this time.

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
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(CURRENT STATUS BY STUDY CATEGORY)

Chemical Name: PHENOTHRIN

Study Category	Study Status
Chronic Feeding - Rat.....	Request for reconsideration under review.
Chronic Feeding - Dog.....	Adequate data on file.
Oncogenicity - Rat.....	Request for reconsideration under review.
Oncogenicity - Mouse.....	Adequate data on file.
Reproduction - Rodent.....	Data submitted under review.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

Chemical Name: ORTHO-PHENYLPHENOL

Study Category	Study Status
Chronic Feeding - Rat.....	Data submitted under review.
Chronic Feeding - Dog.....	Adequate data on file.
Oncogenicity - Rat.....	Adequate data on file.
Oncogenicity - Mouse.....	Adequate data on file.
Reproduction - Rodent.....	Data submitted under review.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

Chemical Name: PHORATE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: PHOSALONE

This Active Ingredient is no Longer Registered.

Chemical Name: PHOSMET

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: PHOSPHAMIDON

This Active Ingredient is no Longer Registered.

Chemical Name: PHOSPHORIC ACID

Health Effects Data are Not Required at This Time.

Chemical Name: PICLORAM

This Active Ingredient is no Longer Registered.

Chemical Name: PINE OIL

There are No Remaining Data Gaps for This Chemical at This Time.

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(CURRENT STATUS BY STUDY CATEGORY)

Chemical Name: PIPERONYL BUTOXIDE TECHNICAL

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: PMA

This Active Ingredient is no Longer Registered.

Chemical Name: PROMETRYN

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: PROPAMOCARB

This Active Ingredient is no Longer Registered.

Chemical Name: PROPARGITE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: PROPETAMPHOS

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: PROPOXUR

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: PROPYZAMIDE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: PYRETHRINS

Study Category	Study Status
Chronic Feeding - Rat.....	Adequate data on file.
Chronic Feeding - Dog.....	Adequate data on file.
Oncogenicity - Rat.....	Adequate data on file.
Oncogenicity - Mouse.....	Adequate data on file.
Reproduction - Rodent.....	Adequate data on file.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Data submitted under review.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

Chemical Name: RESMETHRIN

Study Category	Study Status
Chronic Feeding - Rat.....	Data submitted under review.
Chronic Feeding - Dog.....	Data submitted under review.
Oncogenicity - Rat.....	Adequate data on file.
Oncogenicity - Mouse.....	Data not adequate, may be upgraded.
Reproduction - Rodent.....	Adequate data on file.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
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MANDATORY HEALTH EFFECTS DATA BASE
(CURRENT STATUS BY STUDY CATEGORY)

Chemical Name: ROTENONE

Study Category	Study Status
Chronic Feeding - Rat.....	Request for reconsideration under review.
Chronic Feeding - Dog.....	Request for reconsideration under review.
Oncogenicity - Rat.....	Request for reconsideration under review.
Oncogenicity - Mouse.....	Request for reconsideration under review.
Reproduction - Rodent.....	Request for reconsideration under review.
Teratology - Rat.....	Data not adequate, may be upgraded.
Teratology - Rabbit.....	Request for reconsideration under review.
Mutagenicity - Gene Mutation.....	Request for reconsideration under review.
Mutagenicity - Chromosome Aberration.....	Request for reconsideration under review.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

Chemical Name: SIMAZINE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: SODIUM ARSENITE

This Active Ingredient is no Longer Registered.

Chemical Name: SULFUR

Health Effects Data are Not Required at This Time.

Chemical Name: SULFUR DIOXIDE

Health Effects Data are Not Required at This Time.

Chemical Name: SULFURYL FLUORIDE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: TERBACIL

This Active Ingredient is no Longer Registered.

Chemical Name: TERRAZOLE

This Active Ingredient is no Longer Registered.

Chemical Name: TETRACHLOROPHENOL

This Active Ingredient is no Longer Registered.

Chemical Name: TETRACHLORVINPHOS

Study Category	Study Status
Chronic Feeding - Rat.....	Adequate data on file.
Chronic Feeding - Dog.....	Adequate data on file.
Oncogenicity - Rat.....	Adequate data on file.
Oncogenicity - Mouse.....	Adequate data on file.
Reproduction - Rodent.....	Data not adequate, may be upgraded.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Adequate data on file.

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
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MANDATORY HEALTH EFFECTS DATA BASE
(CURRENT STATUS BY STUDY CATEGORY)

Chemical Name: TETRAMETHRIN

Study Category	Study Status
Chronic Feeding - Rat.....	Adequate data on file.
Chronic Feeding - Dog.....	Data submitted under review.
Oncogenicity - Rat.....	Adequate data on file.
Oncogenicity - Mouse.....	Data submitted under review.
Reproduction - Rodent.....	Adequate data on file.
Teratology - Rat.....	Adequate data on file.
Teratology - Rabbit.....	Adequate data on file.
Mutagenicity - Gene Mutation.....	Adequate data on file.
Mutagenicity - Chromosome Aberration.....	Adequate data on file.
Mutagenicity - DNA Damage.....	Adequate data on file.
Neurotoxicity - Hen.....	Data not required at this time.

Chemical Name: THIABENDAZOLE, HYPOPHOSPHITE SALT

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: THIOBENCARB

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: THIOPHANATE-METHYL

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: THIRAM

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: TOXAPHENE

This Active Ingredient is no Longer Registered.

Chemical Name: TRIADIMEFON

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: S,S,S-TRIBUTYL PHOSPHOTRITHIOATE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: TRIBUTYL TIN BENZOATE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: TRIBUTYL TIN OXIDE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: TRICHLORO-S-TRIAZINETRIONE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: TRICHLOROPHON

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: TRICLOPYR

There are No Remaining Data Gaps for This Chemical at This Time.

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BIRTH DEFECT PREVENTION ACT OF 1984 (SB950)
MANDATORY HEALTH EFFECTS DATA BASE
(CURRENT STATUS BY STUDY CATEGORY)

Chemical Name: TRIFLURALIN

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: TRIFORINE

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: VERNOLATE

This Active Ingredient is no Longer Registered.

Chemical Name: VINCLOZOLIN

There are No Remaining Data Gaps for This Chemical at This Time.

Chemical Name: ZIRAM

There are No Remaining Data Gaps for This Chemical at This Time.

STATUS OF THE DATA

Specific statements are used to report the status of the required health effects data for each pesticide active ingredient in the list that follows. An explanation of each statement used under the column "Status of Data" is given below.

Adequate data on file - The data on file for the study category are adequate, and no additional data are required.

Data submitted under review - Data were received for the study category and are currently being reviewed. The data submitter will be informed of the status when the review is completed.

Request for reconsideration under review - A petition for reconsideration of the acceptability of the study was received and is currently being reviewed. The data submitter will be informed of the status when the review is completed.

Data not adequate - Data on file are not adequate, and may not be upgraded.

Data not adequate, may be upgraded - Data on file are not adequate, but may be upgraded with submission of additional information. A petition for reconsideration has not been received at this time.

No data on file - There are no data on file.

Data not required at this time - Data are not required for this study category at this time.

Commitment to generate data - A commitment was received to initiate the study and submit data by December 31, 1997.

The following is an explanation of the statements used when the individual study categories are not listed under the chemical name:

Health effects data are not required at this time - Adequate data exist to assess potential adverse health effects.

This active ingredient is no longer registered - There are no pesticide products currently registered in California containing this active ingredient.

There are no remaining data gaps for this chemical at this time - All of the required health effects studies were submitted and found to be adequate.

BIRTH DEFECT PREVENTION ACT
REPORT SUMMARY
June 1996

Information on the status of the priority 200 pesticide active ingredients [Food and Agricultural Code Section 13127(a)]

ACTIVE INGREDIENT STATUS	NUMBER OF ACTIVE INGREDIENTS
--------------------------	------------------------------

Identified for the 1986 data call-in	200
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No longer registered	51
Registrations for five were suspended before being withdrawn:	
Cyhexatin	
Dimethylphthalate	
Ferbam	
Naphthalene	
Parathion	

Currently registered	<hr/> 149
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A full set of adequate studies is on file	117
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Studies are not required at this time (adequate data exist to assess potential adverse health effects)	10
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All studies submitted (one or more pending review and/or one or more upgradable)	14
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Active ingredients with data gaps	<hr/> 8
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A full set of adequate studies is not on file	8
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One or more studies are in progress	2
Deadline for submitting data extended to December 31, 1997, as authorized in section 13127.32:	

Methyl Bromide	
Pentachlorophenol	

ACTIVE INGREDIENT STATUS	NUMBER OF ACTIVE INGREDIENTS
--------------------------	------------------------------

Suspension actions taken or pending for all products containing the active ingredient	6
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One or more studies not upgradable: Acrolein ¹	1
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Active ingredients suspended: Bendiocarb Coumaphos	2
--	---

Notices of Intent to Suspend Registration were issued because required data were not submitted by March 30, 1996: Chloroneb Creosote Petroleum Distillates, Aromatic	3
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TOTAL OF 200 ACTIVE INGREDIENTS

Suspension actions taken for one or more products, but not all products containing the active ingredient. These active ingredients are considered to have a full set of valid studies on file for all other products.

Boric Acid²
Diphacinone³
Formaldehyde⁴

¹A request for exemption from the data requirements pursuant to section 13127 (e) (1) is under review.

²Only three boric acid products out of 45 had suspension actions taken.

³Notices of Intent to Suspend Registration for seven of 52 products containing diphacinone were issued because the data requirements for these seven products are different and the data were not submitted by March 30, 1996. The data requirements are different because the registered uses have potentially greater human exposure.

⁴A Notice of Intent to Suspend Registration was issued for one product containing formaldehyde, because the data requirements for this product are different and the data were not submitted by March 30, 1996. The data requirements are different because the registered uses have potentially greater human exposure.

REPORT TO THE LEGISLATURE
BIRTH DEFECT PREVENTION ACT OF 1984

JUNE 1996

The Birth Defect Prevention Act of 1984, as amended, requires the Department of Pesticide Regulation to report annually on the status of specific data gaps remaining for pesticide products containing any active ingredient identified pursuant to Food and Agricultural Code section 13127, subdivision (a). The deadline for submission of data to fill data gaps was March 30, 1996. The registrations of pesticide products containing an active ingredient for which a data gap remains are being suspended. This is the required annual report on data gaps remaining for the priority active ingredients.

This report lists each active ingredient in alphabetical order and shows the status of the health effects data for each required study.

In 1991, the Act was amended (SB 550) strengthening the Director's authority to suspend products for noncompliance and requiring the Director to initiate the suspension process for products containing active ingredients for which all required health effects studies were not submitted by December 31, 1991. Amendments provided that under certain conditions registrants and others could petition for additional time to submit the data. However, the law specifies that no pesticide product containing any of the 200 priority active ingredients for which the required studies have not been submitted by March 30, 1996, shall remain registered. Another amendment requires DPR to report to the appropriate committees of the Legislature on the specific data gaps remaining for the priority 200 active ingredients.

In a March 1996 amendment to the Act, continued registration of two active ingredients is allowed while studies are being completed. The studies for these active ingredients, methyl bromide and pentachlorophenol, are due by December 31, 1997.

REPORT SUMMARY:

Of the 200 priority active ingredients, there remain 149 registered. Most of the 51 active ingredients no longer registered were voluntarily withdrawn by registrants who chose not to support continued registration by providing studies required either by the State or by U.S. EPA. Several active ingredients among these 51 were withdrawn by registrants following product suspension action in California. Several other active ingredients were withdrawn before suspension actions could be taken. For the active ingredients that remain registered, the report identifies those studies on file with adequate data, the studies to be completed for methyl bromide and pentachlorophenol, the studies at DPR pending evaluation, and the studies with inadequate data submitted. Certain studies for which the data were found to be inadequate can be upgraded with the submission of additional information. If studies cannot be upgraded by submission of additional data, the products containing those active ingredients are in the process of being suspended.

The data requirements for antimicrobial pesticide active ingredients (e.g., sanitizers and disinfectants) vary depending on the registered uses. Therefore, for certain antimicrobial products, a complete set of adequate data are on file even though this report shows inadequate or no data for certain study categories. For example, products to which human exposure is determined to be low are required to have on file only one teratogenicity study and three mutagenicity studies.

EXECUTIVE SUMMARY—
of the June 1996 Report to the Legislature

PURPOSE:

This report provides information on the status of the chronic health effects studies required by the Birth Defect Prevention Act (the Act) for the 200 pesticide active ingredients identified as having the most significant data gaps, widespread use, and which were suspected of being hazardous to people. For these 200 priority active ingredients, the required health effects studies were due to the Department of Pesticide Regulation (DPR) by March 30, 1996. Those active ingredients for which pesticide registrants failed to submit the required studies are identified as having data gaps. A "data gap" means that DPR does not have on file adequate health effects studies in the following areas: chronic toxicity, mutagenicity, neurotoxicity, oncogenicity, reproductive effects, and teratology. Pesticide registrants are in compliance with the Act when final reports for required studies are received by DPR, unless later evaluation determines that any study is not adequate.

This is the required annual report to the Legislature on the data gaps that remain for the priority active ingredients, as required by 1991 legislation (SB 550) amending the Act.

BACKGROUND:

The Act requires DPR to acquire certain toxicological data for registered pesticide active ingredients in order to make a scientific determination that their continued uses will not cause significant adverse health effects. Pesticide products containing active ingredients identified as having the potential to cause unmitigated significant adverse health effects will be canceled or suspended.

In January 1986, each registrant of any pesticide product containing any of the 200 priority active ingredients was notified of the required studies needed to fill the data gaps. Many of the studies originally submitted did not meet the U.S. Environmental Protection Agency (U.S. EPA) guidelines for conducting such studies. Because these studies were done some years ago, many registrants were unable to obtain additional data from the laboratories which conducted the original studies; thus, the studies could not be upgraded. Registrants then began contracting with laboratories to begin new studies. However, most registrants failed to complete and submit new chronic health effects studies within the time frames in the law.

CONCLUSIONS:

Of the priority 200 active ingredients, there remain 149 registered. There are 117 active ingredients with a complete set of adequate data on file, and ten active ingredients for which DPR has sufficient data to assess potential adverse health effects. Studies have been submitted to DPR for 14 active ingredients, and are awaiting review. There are six active ingredients with data gaps. Suspension actions have been initiated for products containing five of these, and an exemption request has been received for the other one. Two active ingredients, methyl bromide and pentachlorophenol, have studies in progress, for which the deadline to submit data is December 31, 1997.

The attached table summarizes the June 1996 annual report.

Attachment

